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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte EDWARD H. OVERSTREET, JIAN XIE, MICHAEL S. COLVIN, and MICHAEL A. FALTYS[1]

Appeal 2014-009199
Application 13/588,837
Technology Center 1600

Before RICHARD J. SMITH, TAWEN CHANG, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a system for delivering a therapeutic agent to biological tissue. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] According to Appellants, the real party in interest is Advanced Bionics LLC. (Appeal Br. 2.)

STATEMENT OF THE CASE

Claims on Appeal

Claims 1, 2, 4–13, and 15–21 are on appeal.[2] (Claims Appendix, Appeal Br. 18–21.) Claims 1 and 21 are illustrative and read as follows:

1. A system for delivering a therapeutic agent to biological tissue comprising:

a surgically implantable lead configured to be inserted into the biological tissue, the surgically implantable lead comprising a preformed cavity; and

a modular capsule configured to be retained within the preformed cavity, the modular capsule comprising a first therapeutic agent and a second therapeutic agent, wherein the first therapeutic agent is configured to rapidly elute into the biological tissue and the second therapeutic agent is configured to more slowly elute into the biological tissue; wherein the first therapeutic agent comprises dexamethasone (DEX) salt and the second therapeutic agent comprises dexamethasone base (DXMb).

21. The system of claim 1, wherein the modular capsule comprises:

a membrane permeable to nutrients from biological tissue surrounding the modular capsule; and

genetically engineered cells to accept the nutrients and manufacture a therapeutic drug that diffuses out through the membrane and into the biological tissue surrounding the modular capsule.

Examiner's Rejections

1. Claim 21 stands rejected under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the enablement requirement. (Final Act. 4.)

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[2] Claim 22 is withdrawn from consideration as directed to a non-elected invention (Final Act. dated Dec. 20, 2013, at 2), and claims 3 and 14 are cancelled (Appeal Br. 4).

2. Claims 1, 2, 4, 10, 12, and 20 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan,[3] Heil,[4] Singh,[5] and Campbell.[6] (*Id.* at 5–7.)

3. Claims 5, 13, 16, and 17 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, and Ruane.[7] (*Id.* at 7–9.)

4. Claim 6 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, Ruane, and Helmus.[8] (*Id.* at 9–10.)

5. Claim 7 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, and Wen.[9] (*Id.* at 10.)

6. Claims 8 and 9 stand rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, and Korol.[10] (*Id.* at 10–11.)

7. Claim 11 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, and Stokes.[11] (*Id.* at 11–12.)

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[3] Doan et al., US 6,198,973 B1, issued March 6, 2001 ("Doan").
[4] Heil et al., US 6,304,786 B1, issued Oct. 16, 2001 ("Heil").
[5] Singh et al., US 6,284,804 B1, issued Sept. 4, 2001 ("Singh").
[6] Campbell et al., US 2008/0318918 A1, published Dec. 25, 2008 ("Campbell").
[7] Ruane et al., US 2007/0196423 A1, published Aug. 23, 2007 ("Ruane").
[8] Helmus et al., US 5,447,724, issued Sept. 5, 1995.
[9] Wen, US 2007/0077270 A1, published April 5, 2007.
[10] Korol, US 4,747,845, issued May 31, 1988 ("Korol").
[11] Stokes, US 4,506,680, issued March 26, 1985.

8. Claim 15 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, Ruane, and Korol. (*Id.* at 12.)

9. Claim 18 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, Ruane, and Weidlich.[12] (*Id.* at 12–13.)

10. Claim 19 stands rejected under pre-AIA 35 U.S.C. § 103(a) as unpatentable over Doan, Heil, Singh, Campbell, and Heil '662.[13] (*Id.* at 13.)

FINDINGS OF FACT

We adopt as our own the Examiner's findings and analysis concerning the scope and content of the prior art. The following findings are included for emphasis and reference convenience.

FF 1. Appellants state that "'dexamethasone,' 'dexamethasone alcohol' and 'dexamethasone base' all refer to the same compound, which is CAS 50-02-2," and that those terms are equivalent. (Reply Br. 15–16.)

FF 2. The Examiner finds that Doan teaches a system for delivering a therapeutic agent to a biological tissue, comprising a surgically implantable lead (30) configured to be inserted into the biological tissue, wherein the lead comprises a preformed cavity (36). (Final Act. 5, citing Doan Fig. 3.)

FF 3. The Examiner finds that Doan discloses a modular capsule (38) configured to be retained with the preformed cavity, and that the capsule is provided with a therapeutic agent (a steroid). (*Id.*, citing Doan Fig. 4.)

FF 4. The Examiner finds that Heil discloses an implantable lead similar to Doan, which may be configured to deliver a therapeutic agent via

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[12] Weidlich et al., US 5,103,837, issued April 14, 1992.
[13] Heil et al., 4,819,662, issued April 11, 1989 ("Heil '662").

elution, and that "this steroid eluting therapeutic may comprise a first therapeutic agent configured to rapidly elute into the biological tissue and a second therapeutic agent configured to elute more slowly over time." (*Id.* at 6, citing Heil Abstract and col. 6, ll. 37–52.)

FF 5. The Examiner finds that Heil discloses that "the first and second therapeutics may comprise, respectively, dexamethasone sodium phosphate (a DEX salt) as the rapid release formulation by virtue of its high solubility and dexamethasone acetate as a slow release formulation because of its relatively lower solubility." (*Id.*)

FF 6. Singh teaches that "[s]uitable forms of dexamethasone include dexamethasone alcohol and dexamethasone acetate. Dexamethasone alcohol is the preferred form of dexamethasone." (Singh col. 2, ll. 16–19.)

DISCUSSION

We adopt and agree with the Examiner's findings, analysis, and conclusions set forth in the Final Action (Final Act. 3–14) and Examiner's Answer (Ans. 2–15). We discern no error in the Examiner's rejection of claim 21 for lack of enablement and claims 1, 2, 4–13, and 15–20 as obvious.

Appellants rely on the same arguments for all claims subject to obviousness rejections. (Appeal Br. 11–17; Reply Br. 5–17.) Moreover, while Appellants state that they have presented separate arguments for various independent and dependent claims (Appeal Br. 10), Appellants are reminded that separate argument of claims requires more than merely the use of separate headings and subheadings. *See* 37 C.F.R. § 41.37(c)(1)(iv); *see also In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011).

Rejection No. 1

Issue

Whether a preponderance of evidence of record supports the Examiner's conclusion that claim 21 fails to satisfy the enablement requirement.

Analysis

In rejecting claim 21 for lack of enablement, the Examiner points to the scope of the claim as requiring "genetically engineered cells" that are configured to accept nutrients and manufacture a therapeutic drug. (Final Act. 4.) In view of that scope, the Examiner explains that neither the "specific cells, or even class of cells," nor "the specific therapeutic or even class of therapeutics these cells would manufacture," are disclosed in the Specification. (*Id.*) The Examiner also explains that the Specification does not indicate what instructions would be provided to the cells or what method of engineering would be used to provide those instructions. (*Id.*) The Examiner concludes that the "scant" disclosure in the Specification and "unpredictable nature of genetic engineering" are such that the Specification does not enable an ordinary artisan to practice the invention of claim 21. (*Id.; see also* Ans. 4–6.)

Appellants argue that "[t]he ability to genetically engineer cells and microorganisms to synthesize a therapeutic drug has existed for some time," and cite to several articles as supporting that argument.[14] (Appeal Br. 10.) Appellants argue further that the initial burden is on the Examiner "to establish a reasonable basis for questioning the sufficiency of the

[14] The online citations to those articles may be found at Appeal Br. 10.

disclosure," but that the Examiner "offers no citation or other objective basis" for the conclusion that claim 21 is not enabled. (*Id.*)

We find that the Examiner has the better position. As an initial matter, we find that the Examiner has provided a reasonable explanation as to why the scope of protection provided by claim 21 is not adequately enabled by the description of the invention provided in the Specification. *See In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993). Moreover, we find that the Examiner's explanation was sufficient "to shift the burden to [Appellants] to establish that a person of ordinary skill in the art could have practiced the invention without undue experimentation." *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982).

As the Examiner recognized, "the general field of genetic engineering of cell lines and microorganisms is well-known." (Ans. 4.) The Examiner pointed out, however, the reasons why that fact alone would not enable the full scope of the claimed invention without undue experimentation. (Final Act. 4; Ans. 5–6.) Appellants do not point to the Specification or provide any explanation of how the scope of claim 21 is commensurate with any description in the Specification. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536 (1966). "While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

Here, as the Examiner points out, claim 21 recites "genetically engineer cells" and "a therapeutic drug," but neither are described in the Specification, nor is a particular process set forth for making and using any such cells that manufacture a therapeutic drug in the environment claimed. (Ans. 4.) Appellants point to no disclosure in the Specification sufficient to support a scope of enablement as broad as claim 21. *See In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) ("[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."); *see also Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1196 (Fed.Cir.1999) ("The scope of the claims must be less than or equal to the scope of enablement"). Accordingly, Appellants' Specification fails to enable the skilled artisan to make and use the invention of claim 21 without undue experimentation.

Conclusion

A preponderance of evidence of record supports the Examiner's conclusion that claim 21 fails to satisfy the enablement requirement.

Rejection No. 2

Issue

Whether a preponderance of evidence of record supports the Examiner's conclusion of obviousness under 35 U.S.C. § 103(a).

Analysis

Claim 1

We find that the Examiner has established a prima facie case of obviousness based on the combination of Doan, Heil, and Singh.[15] (Final Act. 5–7; FF 1–6.) In particular, as pertinent to this appeal, we agree with the Examiner that it would have been obvious "to substitute dexamethasone base for dexamethasone acetate in the invention of Heil." (Final Act. 7.) *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416–17 (2007). Moreover, as set forth below, Appellants' do not overcome or rebut that prima facie case.

Appellants argue against the substitution of dexamethasone alcohol (*i.e.*, dexamethasone base) of Singh in place of the dexamethasone acetate of Heil. (Appeal Br. 11–13; Reply Br. 5–15; *see* FF 5, 6.) In particular, Appellants argue that "[i]f dexamethasone alcohol is indeed interchangeable with dexamethasone acetate . . . then there would be no basis for the preference stated in Singh." (Appeal Br. 12; FF 6.) In addition, while Appellants acknowledge that "Singh indicates that dexamethasone acetate is a suitable alternative to dexamethasone alcohol," Appellants argue that Singh "fails to disclose the intended purpose for which dexamethasone is included in his formulation," and thus fails to establish "a suitable alternative in the present use of the instant application." (*Id.* at 12–13.) Appellants also argue that "Heil provides for the use of dexamethasone as one of the alternative therapeutic agents in a one-therapeutic system" and

[15] Appellants acknowledge that the equivalency teaching of Campbell is not significant to the rejection or to arguments against the rejection. (Reply Br. 16.)

that, in the two-therapeutic system, "Heil contemplates *only* dexamethasone acetate as the slow-release therapeutic agent." (Reply Br. 7.)

We are unpersuaded by Appellants' arguments.[16] The fact that Singh refers to dexamethasone alcohol as the preferred form of dexamethasone does not diminish its teaching that dexamethasone alcohol is a suitable alternative to dexamethasone acetate. *See In re Mills*, 470 F.2d 649, 651 (CCPA 1972); *see also Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1380 (Fed. Cir. 2005).

Regarding the intended purpose of Singh and the "present use of the instant application," the Examiner points out that the formulation of Singh is intended for "topical application to the eye, ear or nose." (Ans. 11; *see* Singh Abstract.) Furthermore, it is well settled that '"a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests.'" *In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) (quoting *In re Burckel*, 592 F.2d 1175, 1179 (CCPA 1979)). Here, Singh teaches and fairly suggests that dexamethasone alcohol (*i.e.* dexamethasone base) is a suitable alternative to dexamethasone acetate, such as for application to the ear. Moreover, claim 1 is a system or apparatus claim. As such, the patentability of claim 1 "depends on the claimed structure, not on the use or purpose of that structure." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809 (Fed. Cir. 2002); *see also Hewlett-Packard Co. v. Bausch & Lomb*

[16] We also acknowledge, but are unpersuaded by, Appellants' argument regarding "hindsight bias." (Reply Br. 7.) Here, the Examiner points to specific disclosures in the prior art that give a reason or motivation to make the claimed system, thereby overcoming any concern regarding hindsight bias. *See Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280, 1292 (Fed. Cir. 2012).

Inc., 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("apparatus claims cover what a device *is*, not what a device does"). Accordingly, because claim 1 is not limited to a particular use (*e.g.*, pharmaceutical indication) of the claimed system, Appellants arguments regarding the intended purpose or use of either Singh or the system of claim 1 are unpersuasive.[17]

Appellants' arguments regarding Heil and a one or two therapeutic system are similarly unpersuasive. Heil teaches an embodiment that includes "a combination of the therapeutically active agents, *such as* dexamethasone acetate and dexamethasone sodium phosphate." (Heil col. 6, ll. 37–39, emphasis added.) Heil also teaches the manufacture of various embodiments wherein the coating includes a percentage of soluble particles of dexamethasone (dexamethasone base), dexamethasone acetate, or dexamethasone sodium phosphate. (*Id.*, col 7, ll. 1–28.)[18] Heil thus teaches and suggests the use of dexamethasone base, including in combination with dexamethasone sodium phosphate (a DEX salt), and we are not persuaded that its teachings are limited to a one therapeutic system or a two therapeutic system requiring dexamethasone acetate.

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[17] We acknowledge, but are unpersuaded by, Appellants' arguments regarding the distinction between structural classification and pharmaceutical indication. (Appeal Br. 12–13; Reply Br. 9–14.) For the reasons stated, we discern no error in the Examiner's analysis.

[18] Claims 24 and 29–33 of Heil, which Appellants' recognize was also cited by the Examiner in support of the use of the dexamethasone base (Reply Br. 5–6 (citing Ans. 8)), recite that the coating includes "at least one of" dexamethasone base, acetate or sodium phosphate, indicating that the coating can be any one of dexamethasone base, acetate or sodium phosphate, as well as any combination thereof.

Claim 1 is prima facie obvious. Singh suggests the interchangeability of dexamethasone base (dexamethasone alcohol) with dexamethasone acetate (FF 6), [19] and Heil suggests that dexamethasone base may be used in combination with a dexamethasone salt (dexamethasone sodium phosphate) (Heil cols. 7, 8).

Unexpected Results

Appellants argue that they have discovered "that dexamethasone base is more potent per unit weight than the analogous dexamethasone salt" and that "the discovery that dexamethasone base is preferable to dexamethasone acetate in extended release formulations is an unexpected result." (Appeal Br. 13.) Appellants argue further that "one of ordinary skill in the art would reasonably expect that the pro-drug form of dexamethasone (dexamethasone acetate) would be superior for prolonged release formulations than direct administration of the active species (dexamethasone base)." (*Id.* at 13–14.) In support of that argument, Appellants point to the Specification's discussion comparing DXMb (dexamethasone base) with DEX salt, "which describes dexamethasone base as providing superior prolonged release than dexamethasone salts." (*Id.* at 14, citing Spec. ¶¶ 71–72 and 81.)

We are not persuaded, for at least the following reasons. First, the mere recognition of latent properties in the prior art does not render

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[19] Moreover, Appellants admit that it was known that dexamethasone acetate and base "both have comparably low aqueous solubility." (Appeal Br. 14.) Thus, as the Examiner indicated, while "Heil fails to explicitly disclose the second therapeutic comprises dexamethasone base" as the slow release therapeutic, "[i]t would have been obvious for a person having ordinary skill in the art at the time the invention was made to substitute dexamethasone base [as an equivalent slow release therapeutic] for dexamethasone acetate" (Final Action 6–7, Ans. 11.)

nonobvious an otherwise known invention. *In re Baxter Travenol Labs*, 952 F.2d 388, 392 (Fed. Cir. 1991) (citing cases). The increased potency and prolonged release that Appellants discovered is simply a property of DXMb (dexamethasone base). *See In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) ("From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing.").

Second, "any superior property must be *unexpected* to be considered as evidence of non-obviousness." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1371 (Fed. Cir. 2007). While Appellants argue that the discovered properties are unexpected, Appellants provide no *evidence* that the results are unexpected, and attorney argument cannot take the place of evidence. (Ans. 13–14.) *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

Finally, "objective evidence of nonobviousness must be commensurate in scope with the claims." *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972). Here, Appellants arguments regarding increased potency and prolonged release are advanced in the context of "cochlear leads" and "a spatially-restricted environment." (Appeal Br. 13; Spec. ¶81.) But, as discussed above, claim 1 is not limited to a particular use. Thus, Appellants' arguments and evidence are not commensurate in scope with claim 1 or otherwise persuasive that any distinction between DXMb and DEX salt overcomes or rebuts the prima facie case of obviousness.

Claim 12

Appellants rely on the same arguments advanced in connection with claim 1, and those arguments are unpersuasive for the reasons set forth above.

Rejection Nos. 3 – 10

Appellants rely on the same arguments advanced in connection with Rejection No. 1, and those arguments are unpersuasive for the reasons set forth above.[20]

Conclusion of Law

The Examiner established a prima facie case of obviousness as to claim 1 based on the combination of Doan, Heil, and Singh. Moreover, Appellants' arguments and evidence regarding unexpected results, when weighed with the evidence of obviousness, are insufficient to support a conclusion of nonobviousness. Accordingly, a preponderance of evidence of record supports the Examiner's conclusion that claim 1 is obvious under 35 U.S.C. § 103(a). The rejections of claims 5–9, 11–13, and 15–19 are affirmed for the same reasons as the rejection of claim 1. Claims 2, 4, 10, and 20, which were not argued separately, fall with claim 1.

SUMMARY

We affirm the rejections of all claims on appeal.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

[20] Claim 5 is treated as representative of the claims subject to Rejection No. 3 and Claim 8 is treated as representative of the claims subject to Rejection No. 6.